



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/047,461 | 01/14/2002 | Andras Guttman | 1360.034US1 | 3157 |

25297 7590 02/18/2005

JENKINS & WILSON, PA
3100 TOWER BLVD
SUITE 1400
DURHAM, NC 27707

EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT PAPER NUMBER

1753

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/047,461 | Applicant(s) GUTTMAN ET AL. | |
| | Examiner Jeffrey T. Barton | Art Unit 1753 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 49-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 49-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>20021112, 20030905</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 20031215, 20040730</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-16 and 49-61, in the reply filed on 15 December 2004 is acknowledged. Because applicant did not point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1753

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-13, 15, 16, and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finney et al in view of Rice et al.

Regarding claims 1 and 49, Finney et al disclose an electrophoresis system comprising two buffer reservoirs with electrode terminals (Figure 1, reservoirs 40 and 50 with terminals visible on their near ends); and a chamber coupled to the reservoirs (defined by spacer 20) having a bottom plate (30) and top plate (11) in parallel alignment and holding separation medium therein. (Column 15, lines 2-8)

Regarding claims 2-6, Finney et al disclose using glass top and bottom plates, with variable thickness, separated from each other by as little as 100 microns. (Column 10, lines 31-40; Column 14, lines 40-55; Column 15, lines 6-14)

Regarding claim 7, the buffer reservoir bodies (40 and 50) can be called "covers", as they cover portions of the top and bottom plates 11 and 30.

Regarding claim 13, Finney et al disclose a band detector. (Column 17, lines 1-10)

Regarding claims 15 and 16, Finney et al disclose the terminals being connected to poles of a power supply. (Column 11, lines 7-19)

Relevant to claim 53, Finney et al disclose the separation medium being a gel.
(Title)

Specific to the combination to be made, Finney et al disclose forming sample wells using a comb that provides regularly-spaced wells in the gel. (Figure 3) The comb is applied via apertures in the bottom of the cathode buffer reservoir. (Column 12, lines 30-53) Samples are disclosed as being manually or automatically applied to the gel via these wells.

Finney et al do not explicitly disclose a system comprising a sample delivery device having a longitudinal axis and having a plurality of tabs extending orthogonally from this axis, the device being adapted to couple with an opening of a reservoir of the device.

Rice et al disclose a membrane loader for use in applying samples to electrophoresis gels (e.g. Figure 6a), which has a longitudinal axis with a plurality of tabs extending orthogonally from this axis, the loader adapted to couple to an opening corresponding to a sample loading position within an electrophoresis cassette. (e.g. Figure 1a)

Art Unit: 1753

Relevant to claims 8-10 and 50-52, the membrane loader includes a nanoporous membrane. (Examples given in the Table of Columns 13-16 - pores as small as 50 nm in No. 33)

Relevant to claims 11 and 12, Rice et al disclose more than five tabs. (Figure 6a) They also disclose 2.5 mm wide tabs with 1 mm spacing between them (Column 13, lines 1-7). (i.e. 3.5 mm/tab over the length of the loader)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Finney et al by using the membrane loader of Rice et al to load samples into the gel, because Rice et al teach that it simplifies sample loading onto gels by reducing the dexterity required and that it also reduces loading time, among other benefits. (Column 6, line 60 - Column 7, line 1; also the Background section details drawbacks of the prior methods)

In such a combination, it could accurately be said that the sample delivery device (membrane loader) is coupled with openings of the cathode reservoir, as the tabs would be inserted through the same apertures within the reservoir base that held the comb in the gel molding step. (Column 12, lines 30-53; Figure 3)

Further addressing claim 5, choice of any specific plate spacing would be within the abilities of one having ordinary skill in the art, depending on the specific experiment to be run.

Further addressing claim 12, given the disclosed width of the gels of Finney et al (20-30 cm; Column 10, lines 31-37) and the tab spacing disclosed by Rice et al (3.5 mm/tab), there would be about 57-86 tabs on this loader.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Finney et al and Rice et al as applied to claim 1 above, and further in view of Zhang et al.

Finney et al and Rice et al disclose systems as described above in addressing claim 1. Finney et al also suggests using known methods of detection for analyzing the gels. (Column 17, lines 1-11)

Neither Finney et al nor Rice et al explicitly disclose using an optical densitometer for detection.

Zhang et al disclose a slab gel electrophoresis system, in which they use an optical densitometer to produce an image of the stained gel. (Column 11, lines 6-11)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the system of Finney et al and Rice et al by using a optical densitometer for spot detection, as taught by Zhang et al, because Finney et al disclose that their system can be used with known prior art detection methods (Column 17, lines 1-11) and Zhang et al teach the usefulness of optical densitometry in producing an electronic image of the gel for storage and later analysis.

7. Claims 54-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finney et al and Rice et al as applied to claim 49 above, and further in view of Johansson et al.

Finney et al and Rice et al disclose systems as described above. Finney et al disclose no particular gel to be used in their cassette, referring only to a generic gel material. (e.g. Column 4, line 56 - Column 5, line 7)

Neither Finney et al nor Rice et al explicitly disclose using media of the claimed compositions or media adapted for separation of molecules of these molecular weight ranges.

Johansson et al disclose using mixtures of agarose and linear polyacrylamide to separate plasma proteins. The agarose percentage falls in the specified range (Paragraph bridging pages 202 and 203), as does the acrylamide percentage. (Figure 2, Page 206-207) The globulins separated also fall within the claimed molecular weight ranges. (γ - and α_2 - β -globulin)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the system of Finney et al and Rice et al by using a mixed agarose/linear polyacrylamide matrix, as taught by Johansson et al, because Finney et al specifies no gel to be used with their system, suggesting that gels known in the prior art would be suitable. Furthermore, Johansson et al teach the advantages of the mixed agarose/LPA system in reducing the effects of electroosmosis, obtaining gels with some advantages of both polyacrylamide and agarose, and in some sharpening of

protein bands, in comparison to untreated agarose. (Page 211, 2nd full paragraph - Page 212; Paragraph bridging pages 206 and 207)

Additionally, it would be within the abilities of one having ordinary skill in the art to select a suitable gel from among those known in the prior art for use within the system of Finney et al.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Horowitz et al also teach advantages of mixed agarose/LPA media.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

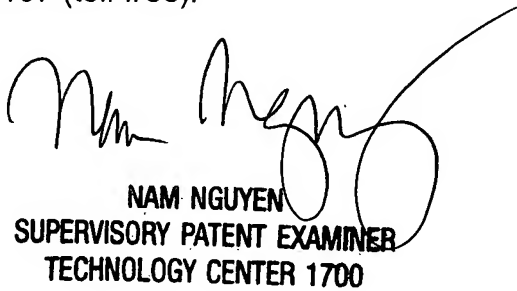
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1753

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
February 14, 2005



NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700